

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA WOMEN'S HEALTH, INC.,	:	Civil Action No. 10-80(FSH)
	:	
Plaintiff,	:	
	:	
v.	:	<u>OPINION and ORDER</u>
	:	
LUPIN, LTD., et al.,	:	October 27, 2010
	:	
Defendants.	:	
	:	

This matter comes before the Court upon Plaintiff Teva Women's Health, Inc.'s ("TWH") Motion to Dismiss Defendant Watson's inequitable conduct counterclaim pursuant to Fed. R. Civ. P. 12(b)(6)¹ and to strike Watson's Affirmative Defense pursuant to Fed. R. Civ. P.

¹ The standard governing a motion to dismiss a counterclaim is the same as the well known standard governing motions to dismiss generally. "To survive a motion to dismiss, a [pleading] must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) ("[S]tating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest the required element. This does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element.") (internal quotations omitted). When considering a motion to dismiss under *Iqbal*, the Court must conduct a two-part analysis. "First, the factual and legal elements of a claim should be separated. The District Court must accept all of the [pleading's] well-pleaded facts as true, but may disregard any legal conclusions. Second, a District Court must then determine whether the facts alleged in the [pleading] are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009) (internal citations omitted). "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a [pleading] suffice if it tenders naked assertions devoid of further factual enhancement." *Iqbal*, 129 S. Ct. at 1949 (internal quotations and alterations omitted).

12(f);² and Defendant Watson having filed an opposition to the motion; and the Court having considered the parties' submissions and decided this matter without oral argument pursuant to Fed. R. Civ. P. 78;

and it appearing that in support of its inequitable conduct counterclaim and affirmative defense, Watson claims that "while obtaining the presently asserted '545 patent, TWH's patent attorneys and other representatives intentionally withheld numerous material documents from the U.S. Patent and Trademark Office ("USPTO"), all of which were produced to TWH during TWH's ongoing patent litigation in Nevada against Watson alleging infringement of the closely-related '969 patent. The withheld litigation documents explain why the invention claimed in the '545 patent is obvious in light of the prior art;"

and the Court noting that each person involved in filing and prosecuting a patent

² The same standard governs the motion to strike the affirmative defenses under Rule 12(f). *See In re Gabapentin Patent Litig.*, 648 F. Supp. 2d 641, 647-48 (D.N.J. 2009) ("Because a motion [to strike] challenges the legal sufficiency of the pleading, it is governed by the same standards as a motion to dismiss[.] ... An affirmative defense is insufficient as a matter of law if it cannot succeed under any circumstances."). Striking an affirmative defense "is a drastic remedy, to be resorted to only when required for the purposes of justice." *In re Gabapentin Patent Litig.*, 648 F. Supp. 2d 641, 648 (D.N.J. 2009); *see also Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 188 (3d Cir. 1986) ("[A] court should not grant a motion to strike a defense unless the insufficiency of the defense is clearly apparent. The underpinning of this principle rests on a concern that a court should restrain from evaluating the merits of a defense where ... the factual background for a case is largely undeveloped.") (internal citations and quotations omitted); *cf. Garlanger v. Verbeke*, 223 F. Supp. 2d 596, 609 (D.N.J. 2002) ("[M]otions to strike are usually viewed with disfavor and will generally be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues.") (internal quotations omitted).

application has a duty of good faith in dealing with the USPTO;³

and the Court noting that TWH argues that the inequitable conduct counterclaim should be dismissed, and the affirmative defense struck, because they fail to meet the pleading standard that Federal Rule of Civil Procedure 9(b) mandates for claims of inequitable conduct;

and the Court noting that in 2009 the Federal Circuit held that inequitable conduct is analogous to fraud, which under Fed. R. Civ. P. 9(b) must be pled with particularity, *see Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009);⁴

and the Court finding that Watson's allegations do not adequately allege inequitable conduct under *Exergen* because under the Fed. R. Civ. P. 9(b) pleading standard, Watson, *inter alia*, has not sufficiently identified the individuals involved or the information withheld and why it was material, nor has it alleged sufficient facts to support TWH's deceptive intent;

³ See *McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007). This duty of good faith includes a “duty to disclose to the Office all information known to that individual to be material to patentability.” *Id.* Any breach of this duty constitutes inequitable conduct and may result in the patent being rendered unenforceable. In establishing a claim of inequitable conduct, a party must demonstrate that the patent applicant “with intent to mislead or deceive the examiner, fail[ed] to disclose material information or submit[ted] material false information to the PTO during prosecution.” *Id.*

⁴ The pleading standard was summarized in *Exergen* as follows:

In sum, to plead the “circumstances” of inequitable conduct with the requisite “particularity” under Rule 9(b), the pleading party must identify the specific who, what, when, where and how of the material representation of omission committed before the PTO. Moreover, although “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

Exergen, 575 F.3d at 1328-29.

and the Court finding that Watson fails to identify “who” committed the alleged inequitable conduct;

and the Court further finding that Watson fails to indicate “where” the material information can be found in the documents they claim were withheld from the USPTO;

and the Court finding that Watson fails to specify “what” claims the withheld information was material to;

and the Court also finding that Watson fails to explain “why” the withheld information is material or “how” it would have been used by the USPTO in assessing patentability;

and the Court further finding that Watson fails to allege that anyone who failed to disclose information to the USPTO acted with the intent to deceive the USPTO,

IT IS THEREFORE on this 27th day of October, 2010,

ORDERED that Plaintiff’s Motion to Dismiss Defendant Watson’s inequitable conduct counterclaim pursuant to Fed. R. Civ. P. 12(b)(6) and to strike Watson’s Affirmative Defense pursuant to Fed. R. Civ. P. 12(f) is **GRANTED**; and it is further

ORDERED that Defendant file an Amended Counterclaim and Affirmative Defense that comply with the stringent pleading requirements set forth by the Federal Circuit in *Exergen* by December 1, 2010.⁵

s/ Faith S. Hochberg
Hon. Faith S. Hochberg

⁵ The Court finds that amendment at this time would not be futile and therefore, it is appropriate to permit Watson the opportunity to do so. *See In re Burlington Coat Factory Securities Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997).